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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,657	02/20/2001	Ulf Landegren	LANDEGREN=1A	5356

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EXAMINER
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CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 01/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/785,657	<b>Applicant(s)</b> LANDEGREN ET AL.	
	<b>Examiner</b> Suryaprabha Chunduru	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 2-7, 13-15 and 17-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-7, 13-15 and 17-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. Applicants' response to the office action filed on June 17, 2004 has been entered.
2. Claims 2-7, 13-15 and 17-25 are pending.

***Priority***

3. The instant application is filed on February 20, 2001 and claims the benefit of US provisional application No. 60/183371, filed on February 18, 2000.

***Response to Arguments***

4. Applicants' response to office action are fully considered and found persuasive.
5. With regard to the rejection made in the previous office action under 35 USC 112 second paragraph Applicants' arguments and amendment are fully considered and found persuasive and the rejection is withdrawn herein in view of amendment.
6. With regard to rejection made under 35 USC 102(b) Applicants' arguments are fully considered and the rejections are withdrawn herein in view of and Applicant's persuasive arguments, and new grounds of rejections.
7. With regard to rejection made under 35 USC 103(a) Applicants' arguments are fully considered and the rejections are withdrawn herein in view of and Applicant's persuasive arguments, and new grounds of rejections.

***New grounds of rejections***

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being

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indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 14-15 are indefinite over the recitation of "capable of interacting or binding" because capability is a latent characteristic and the claims do not set forth the criteria by which to determine capability, that is, the meets and bounds of the claims are unclear. That is, it is not clear whether the recited oligonucleotides / ligands have the potential to interact /bind or do in fact do interact/ bind the to the recited target. Amendment of the claim to read, for example, "which interacts/ which binds" would obviate this rejection.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-7, 13-15, 17-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Landegren (WO 97/00446) in view of Ebersole et al. (WO 97/32044).

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Landegren teaches a method of 25, for detecting one or more analyte(s) (target antigen) in a solution (see page 3, line 9-13, line 31-) wherein the method comprises

(a) binding of two or more proximity probes (oligonucleotides) to a respective binding site (epitopes) on the analyte, wherein the proximity probes comprise a binding moiety (antibody) with affinity for said analyte and nucleic acids (oligonucleotides) acting as a reactive functionality coupled thereto (crosslinkable compounds) (see page 4, line 1-5);

(b) allowing the binding moiety to bind one or more analytes, and allowing the nucleic acids (oligonucleotides) to interact with each other by base pairing if they are in close proximity to each other (see page 4, line 1-5, line 26-37);

(c) detecting the degree of interaction between the nucleic acids (see 33-37, page 5, line 11-14).

With regard to claim 2, 19-20, Landegren teaches that said interaction comprises amplification of the interacted nucleic acids and quantitation of the amplification product (see page 4, line 7-8, page 7, line 20-35);

With regard to claim 3, 23, Landegren teaches that the binding moiety is selected from protein (monoclonal and polyclonal antibodies)(see page 5, line 29-33);

With regard to the claim 4, 26-27, Landegren teach that the analyte (s) are selected from proteins (myoglobin, human growth hormone) (see page 6, line 22-25, page 7, line 15-20);

With regard to claim 5, Landegren teaches that the binding sites for the binding moieties of the proximity probes are situated on the same analyte (see page 4 line 1-5);

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With regard to claim 6, Landegren teaches that said binding moieties are antibodies and said antibodies each bind to one or more analytes via binding specificity for said analytes(s) (see page 4, line 1-5);

With regard to claim 7, 23, Landegren teaches that said interaction of nucleic acids (oligonucleotides) coupled to the binding moieties is through hybridization to a common template and ligation of the nucleic acid free 3' and 5' ends (see page 5, line 4-19);

With regard to claim 14, Landegren teaches that the first proximity probe comprises purified analyte coupled to an oligonucleotide (see page 3, line 31-37, page 4, line 1-5 wherein the analyte is purified using a first antibody specific for said analyte, and then coupled to the oligonucleotides).

However Landegren et al. did not teach detection of analyte in solution or analyte not immobilized on a solid support.

Ebersole et al. teach a homogeneous detection probe system which requires detection without immobilization of the analyte/probe, wherein the method comprises probes in close proximity facilitate energy transfer and signal modification of the reporter moieties thereby detecting the signal without any alteration of signal generation potential (see page 17, line 4-31). Ebersole et al. also teaches that the method facilitates detection of analyte directly in solution without the need for target immobilization, and also provides real-time detection of the analyte (see page 17, line 29-31, page 19, line 1-7). Ebersole et al. teach that the method comprises detection of analyte from infectious agents, in food and environment (see page 1, line 14-18); highthroughput assay format for detecting analyte(s) (see page 25, line 35-38).

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Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to combine a method for detecting one or more analytes as taught by Landegren with method for detecting analyte in a solution phase (homogeneous detection probe system), to achieve expected advantage of developing an improved and sensitive method for detecting a target analyte because Ebersole taught that the invention enables the detection of analyte directly in solution without the need for target immobilization , and also provides real-time detection of the analyte (see page 17, line 29-31, page 19, line 1-7). An ordinary practitioner would have motivated to combine the method of Landegren with the incorporation of homogeneous detection probe as taught by Ebersole et al. for purpose of developing a simple inexpensive and real-time sensitive method for detecting analyte(s) in a sample.

### *Conclusion*

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

*SPE*  
SURYAPRABHA CHUNDURU  
January 4, 2005

*✓*  
JEFFREY FREDMAN  
PRIMARY EXAMINER  
1/5/05